PATENT COOPERATION TREATY

PCT

REC'D 13 SEP 2005

WIPO PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Appli	cant's	or agent's	s file reference	FOR FURTHER	ACTION	See Form PCT/IPEA/416						
PCT	/IB20	applicat 04/001(035	International filing da		Priority date (day/month/year) 11.04.2003						
Intern B328	iational B27 <i>[</i> 2]	Patent (8, B32E	Classification (IPC) or na 333/00, B32B23/08	ational classification an , C08L101/00	d IPC							
Applic CSIF						<u></u>						
	Authority under Article 35 and transmitted to the applicant according to Article 36.											
2.	I nis F	REPORT	consists of a total o	f 7 sheets, including	this cover sheet.							
3.	This report is also accompanied by ANNEXES, comprising:											
	a. 🔼 sent to the applicant and to the International Bureau) a total of (sheets, as follows:											
	and/or sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the											
		☐ sh be Su	eets which supersed yond the disclosure i pplemental Box.	e earlier sheets, but n the international a	which this Authority co oplication as filed, as i	onsiders contain an amendment that goes ndicated in item 4 of Box No. I and the						
	ь. 🗆	Box He	lating to Sequence L	isting (see Section 8	302 of the Administration	nber of electronic carrier(s)) , containing a rm only, as indicated in the Supplemental ve Instructions).						
4.	This re	port cor	ntains indications rela	ating to the following	items:							
	⊠ Bo	k No. I	Basis of the opini	on								
	Ј Во	k No. II	Priority									
	_	No. III	Non-establishme	nt of opinion with reg	ard to novelty, invention	e step and industrial applicability						
_	_	No. IV	Eack of drifty of III	ivention		ł						
Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement												
L	_	No. VI	Certain document	ts cited								
Box No. VII Certain defects in the international ap					olication							
	т вох	No. VII	l Certain observation	ons on the internation	nal application							
Date of submission of the demand					Date of completion of	this report						
09.11.2004					09.09.2005							
Name ai	nd mai	ing addr	ess of the international		Authorized Officer							
preliminary examining authority: European Patent Office - P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk - Pays Bas Tel. +31 70 340 - 2040 Tx: 31 651 epo nl Fax: +31 70 340 - 3016					Derz, T Telephone No. +31 70	340-3159						
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INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No. PCT/IB2004/001035

	Box No. I Basis of the re	port								
1.										
		e, this report is based on the international application in the language in which it was								
	This report is based on which is the language or	translations from the original language into the following language , f a translation furnished for the purposes of:								
	publication of the inte	(under Rules 12.3 and 23.1(b)) ernational application (under Rule 12.4) ary examination (under Rules 55.2 and/or 55.3)								
2.	With regard to the elements have been furnished to the re	* of the international application, this report is based on (replacement sheets which eceiving Office in response to an invitation under Article 14 are referred to in this dare not annexed to this report):								
ı	Description, Pages									
	2-6, 8-15	as originally filed								
1	1,7	filed with telefax on 21.01.2005								
c	Claims, Numbers									
2	-16, 18-36	as originally filed								
1	, 17	filed with telefax on 21.01.2005								
	a sequence listing and/or	any related table(s) - see Supplemental Box Relating to Sequence Listing								
3. □	The amendments have re	sulted in the cancellation of:								
	☐ the description, pages☐ the claims, Nos.									
	☐ the drawings, sheets/fig	as a second								
	☐ the sequence listing (e	Decify):								
	any table(s) related to									
4. ☐ ha Su	4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the									
	☐ the description, pages ☐ the claims, Nos. ☐ the drawings, sheets/fig ☐ the sequence listing (sp	s ·								
	any table(s) related to s	equence listing (specify):								
*	If item 4 applies, s	ome or all of these sheets may be marked "superseded."								
		"superseded."								

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No. PCT/IB2004/001035

1. In response to the invite	of invent		
restricted the claims	ation to res	trict or pay	y additional fees, the applicant has:
☐ paid additional fees.			
paid additional fees	under prote	est.	
☐ neither restricted no	r paid addit	ional fees.	•
			unity of invention is not complied with and chose, according t
This Authority considers that is	the require	ement of u	unity of invention in accordance with Rules 13.1, 13.2 and 13.
☐ complied with.			
not complied with for the	following	reasons:	
see separate sheet	_		
4. Consequently, this report has	heen esta	ــ : الـــــ طمالط	
☐ all parts.	been esta	roustied iu	respect of the following parts of the international application:
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☐ the parts relating to claim	is Nos		
Box No. V Reasoned state			
	ement unc explanatio	ler Article ns suppoi	e 35(2) with regard to novelty, inventive step or industrial rting such statement
	ement unc explanatio	ier Article ns suppoi	35(2) with regard to novelty, inventive step or industrial rting such statement
		der Article ns suppor Claims Claims	e 35(2) with regard to novelty, inventive step or industrial orting such statement 1-36
1. Statement	Yes:	Claims Claims	
Statement Novelty (N)	Yes: No: Yes: No:	Claims Claims Claims	1-36
Statement Novelty (N) Inventive step (IS) Industrial applicability (IA)	Yes: No: Yes: No: Yes: No:	Claims Claims Claims Claims	1-36 1-36
1. Statement Novelty (N) Inventive step (IS) Industrial applicability (IA) 2. Citations and explanations (Ru	Yes: No: Yes: No: Yes: No:	Claims Claims Claims Claims	1-36 1-36
Statement Novelty (N) Inventive step (IS) Industrial applicability (IA)	Yes: No: Yes: No: Yes: No:	Claims Claims Claims Claims	1-36 1-36
1. Statement Novelty (N) Inventive step (IS) Industrial applicability (IA) 2. Citations and explanations (Ru	Yes: No: Yes: No: Yes: No:	Claims Claims Claims Claims	1-36 1-36
1. Statement Novelty (N) Inventive step (IS) Industrial applicability (IA) 2. Citations and explanations (Rusee separate sheet	Yes: No: Yes: No: Yes: No:	Claims Claims Claims Claims Claims Claims	1-36 1-36 1-36
1. Statement Novelty (N) Inventive step (IS) Industrial applicability (IA) 2. Citations and explanations (Rusee separate sheet Box No. VII Certain defects	Yes: No: Yes: No: Yes: No:	Claims Claims Claims Claims Claims Claims	1-36 1-36 1-36

Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

The following documents referred to in this section are:

D1: US-A-3 997 703 (NAKASHIO SEIZO ET AL) 14 December 1976

D2: EP-A-1.082.215 (TETRA LAVAL HOLDINGS & FINANCE) 14 March 2001

D3: US-A-5 106 890 (MARUHASHI MOTOKAZU ET AL) 21 April 1992

D4: US-A-4 553 973 (EDGREN DAVID) 19 November 1985 (1985-11-19)

1) Novelty

The present application does satisfy the criterion set forth in Article 33(2) PCT because the subject-matter of Claims **1-36** is novel in respect of prior art as defined in the regulations (Rule 64(1)-(3) PCT).

Independent claim 1 defines a packaging material comprising barrier coated *polymer bases*, the barrier layer comprising two blended compatible polymers both being polar and water soluble. The two blended compatible polymers should form an interpenetrating polymer network (IPN) by **interpolymer complexation** (e.g. hydrogen bonding). The **common concept** of the present application is the **problem** of providing water-soluble barrier coatings in packagings **plus its solution**, including the teaching that packaging material barrier coatings can comprise two blended, polar, water-soluble, compatible polymers (IPN).

This is the **common concept** of process claim 17 and all claims 1-36 together. The technical feature "polar" (polymer) is a **redundancy in determination**, resp. an inherently necessary feature for the technical feature water solubility and not an independent and additional feature. All water soluble polymers <u>are</u> polar. Not all the blendable polymers listed in claims 12 resp. 28 will form an interpenetrating polymer network (w.r.t C-IV 7.5).

The one and only example of the application discloses: 7% PVOH + 3% MVE-MAH (methyl vinyl ether - maleic acid copolymer) + 90% water (claims 13, 29).

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY (SEPARATE SHEET)

PCT/IB2004/001035

1. polymer layer

(gas)barrier layer: IPN of two polar and water soluble polymers

The closest prior art has been identified as document D1 and discloses:

The **common concept is novel** in view of **D1** which discloses moulded plastic laminate articles (cf. D1, cl. 6: films, sheets, bottles, containers) which contain at least one barrier blend layer of pullulan (1,4°; -1,6°-Glücan; MW = usuālly 50,000-1.000,000) blended with PVOH in an aqueous solution coated on at least one layer of a corona-treated thermoplastic polymer (PET, PE, PP, PA etc.) which are used for packing material, e.g. for food. Pullulan has a very low gas-permeability. Two-layered molded plastics where the pullulan blend is on the *outside* and three-layered ones (ex. 4 w.r.t. pres. cl. 4-5, res. 20-21) where it is on the inside are disclosed. D1 does not disclose which of the surfaces of the eventual bottle will result in being the coated one. The polymers can be selected from PET, PBT, PC, PAN, PVC, PE, PP and many others. From the list of possible polymers given in present claims 11, 27 and the description page 2, par. 2 only the polymers PETG, PS, PEN, PMP and PB are not disclosed in D1. **D1 is silent whether the polymer blends will form an IPN** and the list of blendable polymers (D1, cl. 8; col. 3, lines 50-68) comprises as well proton donors (e.g. ...acrylic acid) as proton acceptors (e.g. N-vinyl pyrrolidone).

Therewith the teaching of IPNs as barrier layers is absent from D1 - which therewith forms the technically distinguishing feature.

Therewith the subject-matter of claims 1-36 is novel over D1.

The **common concept is novel** over **D3** (claims 1+6, ex. 1, col. 6, lines 2-3, 20 and col. 2, lines 40-60) which discloses a water-soluble PVOH-starch blend coated onto and/or by a hydrophobic resin (PET) and is **silent too whether the polymer blends will form an IPN**.

The subject-matter of claims 1-36 is also novel over prior art **D2** which discloses (D2, claims 2-4, 9) starch based gas barriers in packaging laminates for use as packaging containers. The gas barrier layer can be an **aqueous polymer dispersion** of **starch** or starch derivative + some **PVOH** or **EAA** which provides an **oxygen gas barrier** property of

50 cm3/m2 at 24 h, 1 atm or better, having a dry coating of not more than 7 g/m2 deposited on a plastic layer. D2 is silent about IPNs.

D4 discloses (cl. 1,) a controlled-release drug delivery device, comprising a drug core coated with a cured mixt. of ethyl cellulose, polyhydroxy polymer + carboxyethyl cellulose (EC), a polyhydroxy polymer (I) (hydroxypropyl cellulose (HPC), hydroxypropyl methylcellulose, hydroxyethyl cellulose) and a carboxy polymer (II = carboxypolymethylene (CPM) = copolymer of methyl vinyl ether and maleic anhydride (MVE-g-MAH) or acrylics. Although these polymer blends could form IPNs, D4 is silent about it and the blends are employed as a semipermeable ("osmotic") barrier for the drug. Therewith the subject-matter of claim 1 is novel over D4.

2) Inventive Step

2.1 The present application does satisfy the criterion set forth in Article 33(3) PCT because the subject-matter of independent Claims 1 and 17 does involve an inventive step (Rule 65(1)(2) PCT), because in view of the retrieved prior art it was not obvious, to employ IPNs as barriers for gas (vapour, liquid).

The difference of the subject-matter of independent claim 1 of the present application with respect to the teaching of D1 is that IPNs are employed as gas barrier.

The effect of this difference results in a highly reduced O_2 -transmission rate (comp. pres. appl., tables 1-2 on page 13-14 vs. D1, ex. 1-4, tables 1-2). Even if the results might not by directly comparable (the application refers to "cc/bottle/Day, whereas D1 refers to cc/m².day.atm $^{-1}$) it might be an improvement by a factor 100.

The problem to be solved is therefore to provide a laminate with a good barrier to gases (vapors, liquids) and is solved by packagings having a barrier with the characteristics stipulated in claim 1 of the pres. invention (IPNs of 2 water-soluble polymers).

This problem has not been solved nor suggested or indicated in any document cited in the search report.

2.2) Clarity of the Claims and Support in the Description - Articles 5 & 6 PCT

Not all possible blends listed in claims 12 and 28 will result in IPNs - far from it. The description p. 6, I. 12-19 seems to allow for a huge range of 1:1000 to 1000:1 ratios even for the PVOH + PMVE-MAA blend. Not all of these will result in IPNs either. Viscosity and molar masses might be important criteria for the stability of the IPN's too. However, it is easy for a skilled person, **without undue experimentation**, to determine whether you *have* an IPN, hence there is no undue burden. The inventive idea was to employ IPNs as (better) gas barriers (due to their higher densities and other properties on microscopic level).

Hence the **breadth of the present claims** seems to be allowable under PCT/GL/ISPE/1 5.43 - 5.48 and 5.52.

Claims 2-16 and 18-38 are dependent on claims 1 and 17 and as such also meet the requirements of the PCT with respect to novelty and inventive step.

Re Item VII

Certain defects in the international application

3) To meet the requirements of Rule 5.1(a)(ii) PCT, the documents D1 to D4 should be identified in the description and the relevant background art disclosed therein should be briefly discussed.

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NO.888 P.1

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PACKAGING

This invention relates to the packaging of goods or substances in packages or containers, in situations where migration of gases, vapours or liquids into or out of the interiors of the packages or containers is undesirable. More particularly, the invention relates to a packaging material suitable for use as a package or container in such packaging of goods, and to a process for producing such packaging material.

According to the invention there is provided a packaging material which comprises:

a polymeric base component; and

a barrier component which coats and lines a surface of the base component, the barrier component inhibiting migration of gases, vapours and liquids through the base component, and the barrier component comprising a polymeric layer which coats and lines the surface of the base component, the polymeric layer comprising at least two different polymeric species which are polar and which are water soluble, the different species having different chemical compositions and being bound together physically to form an interpenetrating physical network which provides the barrier component, the different chemical species being complementary in that the physical bonding together thereof is by interpolymer complexation.

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It will be appreciated that, in the packaging to which the invention relates, the packaging material will typically be used to form packages or containers for holding or containing goods or substances to be packaged in the interiors thereof, the

Further according to the invention there is a provided a process for producing a packaging material which comprises a polymeric base component and a barrier component which coats and lines a surface of the base component, the barrier component inhibiting migration of gases, vapours and liquids through the base component, the process comprising the step of coating at least one surface of the base component with a barrier component in the form of a polymeric layer which comprises at least two polymeric species which are polar and water soluble, and have different chemical compositions, the layer lining the base component and the coating step causing the polymeric species to form an interpenetrating physical network which provides the barrier component, the polymeric species being complementary in that they form the interpenetrating network by interacting together physically by interpolymer complexation.

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The process may include the step of shaping the base component into a package or container. The coating step may thus take place after the step of shaping the base component into a package or container. The coating step may take place on an inner surface of the package or container. Instead, or in addition, the coating step may take place on an outer surface of the container.

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The coating step may comprise physically adhering the barrier component to the base component by electrostatic bonding. Instead or in addition, the coating step may comprise chemically adhering the barrier component to the base component by covalent bonding.

21-01-2005

CLAIMS:

- A packaging material which comprises: 1.
 - a polymeric base component; and
- a barrier component which coats and lines a surface of the base 5 component,

the barrier component inhibiting migration of gases, vapours and liquids through the base component, and the barrier component comprising a polymeric layer which coats and lines the surface of the base component, the polymeric layer comprising at least two different polymeric species which are polar and which are water soluble, the different species having different chemical compositions and being bound together physically to form an interpenetrating physical network which provides the barrier component, the barrier component being

characterised in that

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- the different chemical species are complementary in that the physical bonding 15 together thereof is by interpolymer complexation.
 - A packaging material as claimed in Claim 1, characterised in that it is in the 2. form of a package or container.
 - A packaging material as claimed in Claim 2, characterised in that the package 3. or container is selected from the group consisting of capsules, blister packages. sachets, envelopes, jerry cans, bottles and jars.

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base component, the barrier component inhibiting migration of gases, vapours and liquids through the base component, the process comprising the step of coating at least one surface of the base component with a barrier component in the form of a polymeric layer which comprises at least two polymeric species which are polar and water soluble, and have different chemical compositions, the layer lining the base component and the coating step causing the polymeric species to form an interpenetrating physical network which provides the barrier component,

the polymeric species are complementary in that they form the interpenetrating physical network by interacting together physically by interpolymer complexation.

the process being characterised in that

- 18. A process as claimed in Claim 17, characterised in that it includes the step of shaping the base component into a package or container.
- 15 19. A process as claimed in Claim 18, characterised in that the coating step takes place after the step of shaping the base component into a package or container.
 - 20. A process as claimed in Claim 18 or Claim 19, characterised in that the coating step takes place on an inner surface of the package or container.
 - 21. A process as claimed in any one of Claims 18 20 inclusive, characterised in that the coating takes place on an outer surface of the container.